



THE COMMISSIONER IS AUTHORIZED
TO CHARGE ANY DEFICIENCY IN THE
FEES FOR THIS PAPER TO DEPOSIT
ACCOUNT NO. 23-0975

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : **Confirmation No. 4399**
Julian BONNERJEA et al. : Attorney Docket No. 2006_0763
Serial No. 10/595,671 :
Filed May 2, 2006 :

ION EXCHANGE CHROMATOGRAPHY
AND PURIFICATION OF ANTIBODIES

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of the references listed on attached form PTO-1449 and any additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for:

- ☒ each U.S. Patent and U.S. Patent application publication;
- ☐ each reference previously cited in the international application PCT/_____; and/or
- ☐ each reference previously cited in prior parent application Serial No. _____.

1a. ☒ This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, or

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

and thus no certification and/or fee is required.

1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

(1) ☐ the certification of paragraph 2 below is provided, **or**

(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

the certification of paragraph 2 below is provided, and

the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

2. It is hereby certified

a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or

b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.

4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:

- a. ☐ a full or partial English language translation submitted herewith,
- b. ☒ a foreign patent office search report (in the English language) submitted herewith,
- c. ☒ the concise explanation contained in the specification of the present application at pages 1-11,
- d. ☐ the concise explanation set forth in the attached English language abstract,
- e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:

5. ☐ A foreign patent office search report citing one or more of the references is enclosed.

6. ☐ Statement Under 37 CFR 1.704(d)

Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart application, and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Respectfully submitted,

Julian BONNERJEA et al.

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January 4, 2007



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INFORMATION DISCLOSURE STATEMENT

FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)
(Use several sheets if necessary)

Date Submitted to PTO: January 4, 2007

ATTY DOCKET NO.
2006_0763SERIAL NO.
10/595,671APPLICANT
Julian BONNERJEA et al.FILING DATE
May 2, 2006

GROUP

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	6,399,750	6/2002	Johansson			
	AB						
	AC						
	AD						
	AE						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	AF	2004/076485	9/2004	WO			
	AG	0 289 129	11/1988	EP			
	AH	0 345 549	12/1989	EP			
	AI						
	AJ						

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	AK	Djuro JOSIC et al., "Analytical and Preparative Methods for Purification of Antibodies", FOOD TECHNOL BIOTECHNOL, vol. 39, no. 3, 2001, pp. 215-226
	AL	Robert L. FAHRNER et al., "Industrial Purification of Pharmaceutical Antibodies: Development, Operation and Validation of Chromatography Processes", BIOTECHNOLOGY AND GENETIC ENGINEERING REVIEWS, INTERCEPT LTD., Andover, GB, vol. 18, July 2001 (7/2001), pp. 301-327
	AM	G. S. BLANK et al., "Expanded bed absorption in the purification of monoclonal antibodies: a comparison of process alternatives", BIOSEPARATION, KLUWER ACADEMIC PUBLISHERS, DORDRECHT, NL, vol. 10, no. 1-3, 2001, pp. 65-71
	AN	P. FÜGLISTALLER, "Comparison of immunoglobulin binding capacities and ligand leakage using eight different protein A affinity chromatography matrices", JOURNAL OF IMMUNOLOGICAL METHODS, vol. 124, no. 2, 1989, pp. 171-178
	AO	"rmp Protein A Sepharose Fast Flow - high purity, high throughput, low leakage, low risk", DOWNSTREAM THIRTY TWO 18-1145-45, 'Online! 2002, XP002357257, Retrieved from the Internet: URL : http://www.jp.amershambiosciences.com/newsletter/downstream/pdf/downstream32.pdf > retried December 1, 2005

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include cop. this form with next communication to applicant.



Sheet 2 of 2

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*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BA						
	BB						
	BC						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO	
	BD							
	BE							
	BF							

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	AG	Harish IYER et al., "Considerations During Development of a Protein A-Based Antibody Purification Process", BIOPHARM, Cleveland, OH, US, vol. 15, no. 1, 2002, pp. 14-16, 18, 20, and 53
	AH	Pete GAGNON, "Affinity Chromatography: The Fine Print", VALIDATED BIOSYSTEMS QUARTERLY RESOURCE GUIDE FOR DOWNSTREAM PROCESSING, 1999,
	BI	Julian BONNERJEA, "Purification of Therapeutic Proteins", METHODS IN MOLECULAR BIOLOGY (Clifton, N.J.), 2004, vol. 244, February 2004 (2/2004), pp. 455-462
	BJ	"Antibody Purification (Handbook, 18-1037-46, Edition AC)", 2002, AMERSHAM BIOSCIENCE
	BK	L. O. NARHI et al., "Effect of Three Elution Buffers on the Recovery and Structure of Monoclonal Antibodies", ANALYTICAL BIOCHEMISTRY, vol. 253, no. 2, November 15, 1997 (11/15/1997), pp. 236-245
	BL	
	BM	

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include cop. this form with next communication to applicant.